

REMARKS

Claims 1-28 are pending and stand rejected. Claims 1, 18, and 25 are amended herein to recite that the chuck comprises a septum contained within the channel. Support for these amendments can be found throughout Applicants' specification. *See*, for example, page 6, line 28 to page 7, line 16. Claim 14 is amended for consistency with claim 1. Claim 22 is amended to recite that the chuck connection device is configured to fit against the chuck and the chuck housing to hold the chuck and the chuck housing together. Support for this amendment can be found in Applicants' specification at, for example, page 10, lines 6-11, which disclose that a chuck connection device can be configured to fit against a chuck and a chuck housing to hold the chuck and the chuck housing together. In addition, the language of the claim of priority to related applications is amended herein. No new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-28.

Specification

The Examiner objected to the disclosure, stating that the term "priority from" in the priority claim should read "benefit of." Applicants respectfully note that there is no specific language requirement in the M.P.E.P. or the C.F.R. for a claim of priority to related applications. To further prosecution, however, Applicants have amended the claim of priority to include the term requested by the Examiner. In light of this amendment, Applicants respectfully request withdrawal of the objection to the specification.

Rejections under 35 U.S.C. § 112

The Examiner rejected claims 2, 3, and 22-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Examiner alleged that it is unclear whether the chuck recited in claims 2 and 3 actually includes a septum. The Examiner further alleged that claims 22-24 are incomplete for omitting structural cooperative relationships between the "chuck connection device" and the "applicator chuck."

To further prosecution, Applicants have amended claim 1 herein to recite that the brachytherapy applicator chuck comprises a septum contained within the channel. Thus, it is clear that the chuck recited in claims 2 and 3 contains a septum. In addition, Applicants have amended claim 22 to recite that the chuck connection device is configured to fit against the chuck and the chuck housing to hold the chuck and the chuck housing together. As such, the claims recite a structural cooperative relationship between the chuck and the chuck connection device.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 2, 3, and 22-24 under 35 U.S.C. § 112.

Rejections under 35 U.S.C. §102

The Examiner rejected claims 1, 4-11, 15-18, and 22-24 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,572,527 (the Steele *et al.* patent). With respect to independent claim 1, the Examiner alleged that the Steele *et al.* patent discloses a seed-holding system comprising a transfer device that defines a channel having a proximal end and a distal end, where seeds are dispensed to an applicator “through an applicator bore (element 98 of Fig. 7) or ‘septum’ into an implantation needle (see col. 7, lines 12-17 and Fig. 7).” With respect to independent claim 18, the Examiner alleged that the Steele *et al.* patent discloses a “chuck housing” (element 46 of Fig. 1) and a “chuck” (element 12 of Fig. 1) for delivery of radioactive seeds, where the “chuck” comprises proximal and distal ends with a channel extending therebetween, and where the “chuck” can contain a needle and is engaged by the “chuck housing” via disk protrusions (elements 26 and 28 of Figs. 4A and 4B).

The Examiner also rejected claims 1 and 4-23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No 6,656,107 (the Pedersen *et al.* patent). The Examiner stated, *inter alia*, that the Pedersen *et al.* patent discloses a brachytherapy applicator having a channel that is capable of being “adapted to” contain a needle and, since the instantly claimed housing may contain at least part of the seed magazine, the slot disclosed by the Pedersen *et al.* patent (element 30 of Fig. 2) having side surfaces (elements 32 and 34) and a back surface (element 36) thus constitutes a “housing.”

In addition, the Examiner rejected claims 1, 4-9, 11, 15-17, and 25-28 under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,629,960 (the Fontayne patent). In particular, the Examiner stated that the Fontayne patent discloses a radioactive seed "applicator" having proximal and distal ends, defining a channel, and having a needle hub and a needle retention member.

Applicants respectfully disagree with these rejections. The present claims recite a brachytherapy applicator chuck, or an applicator comprising a chuck, that has proximal and distal ends with a channel defined therebetween, wherein the chuck comprises a septum within the channel. A claim is anticipated "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP § 2131. None of the cited references teach each and every element recited in the present claims. For example, the Steele *et al.* patent fails to teach any device containing a septum within a channel. In contrast to the Examiner's statements, element 98 of Figure 7 is not a septum within a channel. Rather, element 98 is simply a bore. Thus, the Steele *et al.* patent fails to teach all elements of the instant claims, and as such does not anticipate the presently claimed devices.

Similarly, neither the Pedersen *et al.* patent nor the Fontayne patent teach each and every element of the present claims. For example, at no point does the Pedersen *et al.* patent or the Fontayne patent teach a device containing a septum within a channel or anywhere else. Thus, none of the cited references anticipates the presently claimed devices.

In light of the above, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 102(e).

Rejections under 35 U.S.C. §103

The Examiner rejected claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentable over the Steele *et al.* patent in view of U.S. Patent No 6,183,461 (the Matsuura *et al.* patent). The Examiner stated that while the Steele *et al.* patent does not teach a septum comprising an elastomeric material, the Matsuura *et al.* patent teaches a drug delivery device having a septum (also referred to as a "valving member" (element 42 of Fig. 3)). The Examiner further stated that the "push rod" of the Steele *et al.* patent "will slide back and forth through the applicator bore or

'septum,' while the septum or valving member of Matsuura *et al.* allows for multiple insertions via the resealing mechanism of its biocompatible elastomeric material." Thus, the Examiner concluded that it would have been obvious to make the device of Steele *et al.* to include the septum of Matsuura *et al.*

Applicants respectfully disagree. The Steele *et al.* patent in combination with the Matsuura *et al.* patent provides no motivation to make the presently claimed devices. Contrary to the Examiner's statements, the Steele *et al.* patent does not disclose a device having a septum contained within a channel. In fact, at no point does the Steele *et al.* patent suggest the need for a septum in a brachytherapy applicator chuck. This is particularly true given that the Steele *et al.* patent makes no mention of blood or other bodily fluid or cells entering the device disclosed therein.

The device disclosed by Matsuura *et al.* is not at all related to the brachytherapy devices recited in the present claims. Rather, as noted by the Examiner, the Matsuura *et al.* patent discloses a device for drug delivery in a body cavity. The device can include a septum seal through which a needle can be inserted to fill the device with fluid *in vivo*. The valve can be pierced one or more times to allow access to the interior of the device, while resealing after the needle is removed. See, column 3, lines 23-37, and column 8, line 67 to column 9, line 3. Thus, the device of Matsuura *et al.* is configured to retain a drug within its interior, such that the drug does not leak out into the body. At no point does the Matsuura *et al.* patent suggest that a septum should be placed into a brachytherapy applicator chuck for any purpose, let alone for the purpose of preventing blood or other bodily fluids from entering the chuck. As such, a person of ordinary skill in the art reading the Steele *et al.* and Matsuura *et al.* patents would not have been motivated to make the brachytherapy applicator chuck recited in the present claims.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 2 and 3 under 35 U.S.C. § 103(a).

The Examiner rejected claims 12-14 under 35 U.S.C. § 103(a) as being unpatentable over the Steele *et al.* patent in view of U.S. Publication No. 2002/0107483 (the Cook publication). The Examiner stated that while the Steele *et al.* patent does not disclose vents to permit exit of air or contaminants from the device, the Cook publication discloses a piercing system having a

vent that allows air to escape from a housing and allows fluid withdrawn through a needle tip to escape and be contained within the vent. Thus, the Examiner concluded that it would have been obvious to make the device of Steele *et al.* to include the vent of Cook.

Applicants respectfully disagree. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974); M.P.E.P. § 2143.03. Claims 12-14 depend from claim 1, and thus recite a brachytherapy applicator chuck having proximal and distal ends with a channel defined therebetween, wherein the chuck comprises a septum within the channel. As noted above, the Steele *et al.* patent contains no teaching or suggestion that a brachytherapy applicator chuck should contain a septum within a channel. The Cook publication does not remedy the deficiencies of the Steele *et al.* patent. For example, at no point does the Cook publication teach or suggest any device containing a septum. Thus, the Steele *et al.* patent and the Cook publication, either alone or in combination, fail to teach or suggest all of the limitations of the instant claims. As such, this combination of references does not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 12-14 under 35 U.S.C. § 103(a).

The Examiner rejected claim 24 under 35 U.S.C. § 103(a) as being obvious over the Pedersen *et al.* patent in view of the Steele *et al.* patent. The Examiner stated that while the Pedersen *et al.* patent does not teach a device for retaining a radiation shield, "any device can be 'configured to' retain a radiation shield." The Examiner further stated that the device disclosed in the Steele *et al.* patent can further include a shield to provide radioactive shielding around the seed holder, and that the "chuck connection device" disclosed in the Pedersen *et al.* patent comprises a structure (element 40 of Fig. 3) that can protrude from the back surface of the slot (element 30) or "chuck housing" to connect it to the chuck, thus constituting a "chuck connection device." In addition, the Examiner asserted that this slot receives the seed holder and thus comprises a "shield" around the holder. Thus, the Examiner concluded that it would have been obvious to make the "chuck connection" device of Pedersen *et al.* to include the radiation shielding of Steele *et al.*

Applicants respectfully disagree. Claim 24 depends from claim 22, which depends from claim 18. Thus, claim 24 recites a brachytherapy applicator comprising a chuck and a chuck housing, wherein the chuck comprises a proximal end and a distal end with a channel defined therebetween, wherein the chuck contains a septum within the channel, wherein the chuck housing is configured to engage the chuck, wherein the applicator further comprises a chuck connection device configured to fit against the chuck and the chuck housing to hold the chuck and the chuck housing together, and wherein the chuck connection device is configured to retain a radiation shield. As noted above, neither the Pedersen *et al.* patent nor the Steele *et al.* patent teaches or suggests any device containing a septum. Thus, the Pedersen *et al.* patent and the Steele *et al.* patent, either alone or in combination, fail to teach or suggest all of the limitations of the present claims. As such, this combination of references does not render claim 24 obvious.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 24 under 35 U.S.C. § 103(a).

Double Patenting

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of the Pedersen *et al.* patent. The Examiner stated that claim 1 of the Pedersen *et al.* patent and present claim 1 both recite a "brachytherapy chuck defining a channel (slot) where the chuck is capable of containing a needle and septum."

Applicants respectfully disagree. Present claim 1 recites a brachytherapy applicator chuck defining a channel, wherein the chuck comprises a septum contained within the channel. In contrast, claim 1 of the Pedersen *et al.* patent does not recite a septum. Thus, the presently claimed device is not an obvious variant of the device recited in claim 1 of the Pedersen *et al.* patent, and a double patenting rejection is not warranted.

In light of the above, Applicants respectfully request withdrawal of the rejection of claim 1 for obviousness-type double patenting.

CONCLUSION

Applicants submit that claims 1-28 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Applicants believe that no fee is due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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